

§ 40.231

to conduct alcohol screening tests under this part. You may use an ASD that is on the NHTSA CPL for DOT alcohol tests only if there are instructions for its use in this part. An ASD can be used only for screening tests for alcohol, and may not be used for confirmation tests.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41954, Aug. 9, 2001]

§ 40.231 What devices are used to conduct alcohol confirmation tests?

(a) EBTs on the NHTSA CPL for evidential devices that meet the requirements of paragraph (b) of this section are the only devices you may use to conduct alcohol confirmation tests under this part. Note that, among devices on the CPL for EBTs, only those devices listed without an asterisk (*) are authorized for use in confirmation testing in the DOT alcohol testing program.

(b) To conduct a confirmation test, you must use an EBT that has the following capabilities:

(1) Provides a printed triplicate result (or three consecutive identical copies of a result) of each breath test;

(2) Assigns a unique number to each completed test, which the BAT and employee can read before each test and which is printed on each copy of the result;

(3) Prints, on each copy of the result, the manufacturer's name for the device, its serial number, and the time of the test;

(4) Distinguishes alcohol from acetone at the 0.02 alcohol concentration level;

(5) Tests an air blank; and

(6) Performs an external calibration check.

§ 40.233 What are the requirements for proper use and care of EBTs?

(a) As an EBT manufacturer, you must submit, for NHTSA approval, a quality assurance plan (QAP) for your EBT before NHTSA places the EBT on the CPL.

(1) Your QAP must specify the methods used to perform external calibration checks on the EBT, the tolerances within which the EBT is regarded as being in proper calibration, and the intervals at which these checks must be

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performed. In designating these intervals, your QAP must take into account factors like frequency of use, environmental conditions (*e.g.*, temperature, humidity, altitude) and type of operation (*e.g.*, stationary or mobile).

(2) Your QAP must also specify the inspection, maintenance, and calibration requirements and intervals for the EBT.

(b) As the manufacturer, you must include, with each EBT, instructions for its use and care consistent with the QAP.

(c) As the user of the EBT (*e.g.*, employer, service agent), you must do the following:

(1) You must follow the manufacturer's instructions (see paragraph (b) of this section), including performance of external calibration checks at the intervals the instructions specify.

(2) In conducting external calibration checks, you must use only calibration devices appearing on NHTSA's CPL for "Calibrating Units for Breath Alcohol Tests."

(3) If an EBT fails an external check of calibration, you must take the EBT out of service. You may not use the EBT again for DOT alcohol testing until it is repaired and passes an external calibration check.

(4) You must maintain records of the inspection, maintenance, and calibration of EBTs as provided in § 40.333(a)(2).

(5) You must ensure that inspection, maintenance, and calibration of the EBT are performed by its manufacturer or a maintenance representative certified either by the manufacturer or by a state health agency or other appropriate state agency.

§ 40.235 What are the requirements for proper use and care of ASDs?

(a) As an ASD manufacturer, you must submit, for NHTSA approval, a QAP for your ASD before NHTSA places the ASD on the CPL. Your QAP must specify the methods used for quality control checks, temperatures at which the ASD must be stored and used, the shelf life of the device, and environmental conditions (*e.g.*, temperature, altitude, humidity) that may affect the ASD's performance.